REMARKS

I. Introduction

Claims 25 – 31 are presently pending and are rejected. Following entry of the present amendment, claims 25 and 30 are amended. New claims 32-37 are added.

Support for the amendment to claims 25 and 30 may be found in the abstract, paragraphs [0001], [0005], [0003], and [0052], and originally filed claim 1 (now canceled). Support for the amendment to claim 25 may also be found at paragraph [0004]. Support for the newly added claims can be found in paragraphs [0001], [0052] and [0053], and [0061] to [0063].

It is believed no new matter has been added.

II. 35 USC § 112, first paragraph rejection

Claims 25 and 30 are rejected under 35 USC § 112, first paragraph. The Examiner finds that while the present invention is enabled for a method of *treatment* of symptoms or pathologies associated with androgen signaling, the specification does not enable any person skilled in the art to prepare a method of *prevention* of symptoms or pathologies associated with androgen signaling.

Applicants respectfully traverse the rejection; however, in an effort to expedite prosecution have amended claims 25 and 30 to limit the methods to reduce incidence risk, and request that the rejections be withdrawn.

III. 35 USC § 102 rejection

Claim 25 is rejected under 35 USC 102(a) as being anticipated by Lorant et al. (US 6,623,769). The Examiner asserts Lorant discloses an effective amount of lycopene is administered to a subject for a condition associated with androgen signaling. In particular, the Examiner asserts that Lorant teaches the use of lycopene for symptoms and diseases, such as acne, which the Examiner asserts are inherently associated with androgen signaling. The Examiner also argues that the originally filed and amended claims filed on March 5, 2008 encompassed preventing any and all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling.

Applicants respectfully request reconsideration, in view of the amendments to claim 25 and 30.

The present invention is directed to method of incidence risk reduction of pathologies associated with androgen signaling, which comprises administering to a subject at elevated risk for pathologies associated with androgen signaling an effective amount of lycopene to reduce androgen signaling.

Lorant discloses lycopene inhibits the expression of proteases of the extracellular matrix, i.e., metalloproteinases. It is silent as to reducing androgen signaling.

Lorant discloses an acne treatment (see Column 3, lines 5-8), and cites Japanese patent publication number JP-2940964 (publication number 03-188019; Application 01-325613 cited in a concurrently filed Information Disclosure Statement). The Japanese publication discloses a composition for the topical application, not an oral dosage form, which works via a 5-alpha reductase pathway to inhibit hair loss and acne. There is no disclosure of lycopene as reducing androgen signaling.

Applicants respectfully submit Lorant fails to teach or suggest incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, or orally administering an amount of lycopene to reduce androgen signaling. Neither the method, nor the effect of the method, nor the target population for the method are in any way disclosed or inherently addressed by Lorent.

Applicants respectfully request this rejection be withdrawn.

IV. 35 USC § 103(a) rejection

Claims 25 – 31 are rejected under 35 USC 103(a) as being unpatentable over Lorant in view of de Salvert (US 5,827,520). The Examiner finds that Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling, but does not teach the combination of lycopene and vitamin C administered to a subject in need thereof to treat pathologies associated with androgen signaling. However, the Examiner finds de Salvert teaches vitamin C treats pathologies associated with androgen signaling, such as acne, and it would have been obvious to one of skill in the art to modify the teachings of Lorant to include vitamin C as taught by de Salvert.

Applicants respectfully submit that a prima facie case of obviousness has not been established over the claims as presently amended, and request the rejection be withdrawn. The obviousness determination requires four kinds of factual inquiries:

(1) the scope and contents of the prior art;

(2) the differences between the prior art and the claims at issue;

(3) the level of ordinary skill in the pertinent art; and

(4) any objective indicia of success such as commercial success, long felt need, and copying.

KSR Int'l. Co., 127 S. Ct. at 1735 (citing *Graham v. John Deere Co.*, 383 US 1, 17-18 (1966)).

1. The scope and content of the Prior Art and Differences Between the Prior Art and Claimed Invention:

The present invention is directed to methods of incidence risk reduction of pathologies associated with androgen signaling, and non-cancerous symptom and/or pathologies sensitive to lycopene, which comprises administering to a subject at elevated risk for pathologies associated with androgen signaling an effective amount of lycopene to reduce androgen signaling.

The disclosure of Lorant has previously been discussed. Lorant fails to teach or suggest incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, or orally administering an amount of lycopene to reduce androgen signaling.

de Salvert discloses dermatologically active compositions containing ascorbic acid and/or retinol, but fails to teach or suggest incidence risk reduction of pathologies associated with androgen signaling, or orally administering an amount of lycopene to reduce androgen signaling.

2. The Obviousness Determination:

Lorant and de Salvert fail to teach or suggest all of the limitations of the claims.

The present invention is directed to incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, comprising administering an effective amount of lycopene to reduce androgen signaling. Lorant fails to teach or suggest such risk reduction and de Salvert fails to cure such deficiency. Neither reference discloses anything at all about androgen signaling, nor selection of patients at elevated risk for pathologies associated with androgen signaling, nor the use of lycopene to reduce this risk.

There is no reasonable expectation of success or motivation in practicing the claimed invention based on the disclosure of Lorant and de Salvert.

As previously stated, none of the references teach or suggest incidence risk reduction of pathologies associated with androgen signaling by orally administering an effective amount of lycopene to reduce androgen signaling. One of skill in the art would not be motivated or have reasonable expectation of success in practicing the claimed invention. One of skill in the art could only provide incidence risk reduction of androgen pathologies with lycopene by recognizing that androgen signaling may be affected by lycopene.

3. Conclusion:

Claims 25 - 31 are not obvious over Lorant in view of de Salvert. Neither reference teaches or suggests incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, by administering an effective amount of lycopene to reduce androgen signaling. In the absence of any teachings about androgen signaling or associated pathologies in these references, there is no reasonable expectation of success or motivation to practice the claimed invention. As the rejection under 35 USC § 103(a) is therefore improper, Applicants respectfully request that it be withdrawn.

V. Summary

Applicants have made a *bona fide* attempt to address all matters raised by the Examiner. Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued. If any remaining matters need to be resolved, Applicants respectfully request an interview with the Examiner prior to any official action being taken by the Office in response to these arguments and amendments in order to facilitate allowance of the pending claims.

Authorization for the fee for one month extension of time and for the request for continued examination pursuant to 37 C.F.R. 1.114 is submitted herewith. It is believed no other fees are presently required. If a fee is required, please charge the same (or credit any refund) to Deposit Account 50-4255.

Respectfully submitted,

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